Notice of Allowability	Application No.	Applicant(s)	
	09/844,684	MIKAYAMA ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *9/7/04; 4/1/05*.

2. ☒ The allowed claim(s) is/are *3, 6, 8, 23-26, 65 - 71, 73 - 88*. RENUMBERED 1, 26, 27, 29-31, 2-8, 9-24

3. ☒ The drawings filed on _____ are accepted by the Examiner. 12/16/04

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

jlr

DETAILED ACTION

1. Applicant's amendment, filed 9/7/04, has been entered.

Claims 1-2, 4-5, 7, 9-22, 27-29 and 62-64 have been canceled previously.

Claims 3, 6, 8, 23-25, 65 and 67 have been amended.

Claims 79-88 have been added.

Claims 3, 6, 8, 23-26 and 65-88 are under consideration in the instant application.

Claims 30-61 have been withdrawn from consideration as being drawn to non-elected inventions.

Claims 30-61 have been withdrawn from consideration as being drawn to non-elected inventions.

EXAMINER'S AMENDMENT

2. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. ∋ 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

4. Authorization for this Examiner's Amendment was given in a telephone interview with Robert Bedgood on 4/1/05.

5. See the attached **WHAT IS CLAIMED IS:** .

6. The title has been replaced with: -- HUMAN ANTI-CD40 ANTIBODIES -- .

7. An extension of time under 37 C.F.R. § 1.136(a) is required in order to make an Examiner's amendment which places this application in condition for allowance.

During a telephone conversation conducted on 4/1/05, Robert Bedgood requested an extension of time for five (5) months and authorized the Commissioner to charge Deposit Account No.50-2212 the required fee of $2080.00 for this extension and authorized the following Examiner's Amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, It MUST be submitted no later than the payment of the Issue Fee.

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REASONS FOR ALLOWANCE

8. The following is an Examiner's Statement of Reasons for Allowance:

As indicated previously, due to high polymorphism of antibodies, the instant CD40-specific antibodies (and their respective hybridomas / cell lines) are deemed structurally distinct on the primary amino acid basis and therefore free from the prior art. Accordingly the claims of this application are deemed allowable.

9. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 3, 6, 8, 23-26, 65-71 and 73-88 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 6, 8, 23, 24, 26, 65-88 of copending application USSN 10/040,244. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to the same or nearly the same anti-CD40 antibodies. Although the instant claims do not recite cell lines or hybridomas expressing said antibodies, such cell lines expressing antibodies were well known and practiced in the antibody art either in the producing of said antibodies (e.g. monoclonal antibody technology or recombinant antibody technology) at the time the invention was made. Although, the copending claims are drawn to human antibodies and the instant claims do not recite human antibodies per se, it was well practiced and known by the ordinary artisan to employ various antibody forms, including human antibodies in clinical practice. In addition to the interacting with human cell receptors and interactions, human antibodies had the well known advantage of being less immunogenic and of having an increased half-life in human patients.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Given that a provisional double patenting rejection over copending USSN 10/040,244 would be the only rejection remaining in this application; such a provisional obvious double patenting is withdrawn to permit this application to issue. See MPEP 804.

11. Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
April 1, 2005

WHAT IS CLAIMED IS:

1-2. (Canceled)

3. (Currently Amended) A human monoclonal antibody or a CD40-binding fragment thereof, wherein the antibody is denoted number 11, which is produced by hybridoma ATCC PTA-2308.

4-5. (Canceled)

6. (Previously presented) The human monoclonal antibody fragment of any of claims 3 or 79-84, wherein the fragment comprises an scFv, Fab, Fab', or $F(ab')_2$ fragment.

7. (Canceled)

8. (Previously presented) A detectably labeled human monoclonal antibody, wherein the antibody is the antibody of any of claims 3 or 79-81.

9-22. (Canceled)

23. (Previously presented) A pharmaceutical formulation including the antibody of any of claims 3 or 79-84.

24. (Previously presented) A host cell that expresses the antibody of any of claims 3 or 79-84.

25. (Previously presented) A nucleic acid that encodes the antibody of any of claims 3 or 79-84.

26. (Previously presented) A host cell containing the nucleic acid of claim 25.

27-29. (Canceled)

30-61. (Canceled)

62-64. (Canceled)

65. (Currently Amended) A human monoclonal antibody, wherein the antibody comprises the heavy-chain variable sequence and the light-chain variable sequence of the antibody denoted as number 11, which is produced by hybridoma ATCC PTA-2308.

66. (Currently Amended) A human monoclonal antibody, wherein the antibody comprises the heavy-chain variable sequence and the light-chain variable sequence encoded by the pair of sequences set forth as SEQ ID NO: 10 and SEQ ID NO: 11; SEQ ID NO: 12 and SEQ ID NO: 13; or SEQ ID NO: 14 and SEQ ID NO: 15.

67. (Previously presented) A human monoclonal antibody, wherein the antibody comprises a heavy-chain variable sequence and a light-chain variable sequence encoded by heavy and light chain sequences selected from F2-103-heavy chain (ATCC PTA-3302) and F2-103-light chain (ATCC PTA-3303); F5-77-heavy chain (ATCC PTA-3304) and F5-77-light chain (ATCC PTA-3305); and F5-157-heavy chain (ATCC PTA-3306) and F5-157-light chain (ATCC PTA-3307).

68. (Previously presented) A hybridoma denoted as ATCC PTA-2308.

69. (Previously presented) A hybridoma denoted as ATCC PTA-2309.

70. (Previously presented) A hybridoma denoted as ATCC PTA-3337.

71. (Previously presented) A hybridoma denoted as ATCC PTA-3338.

72. (Cancelled)

73. (Previously presented) A cell line denoted as ATCC PTA-3302.

74. (Previously presented) A cell line denoted as ATCC PTA-3303.

75. (Previously presented) A cell line denoted as ATCC PTA-3304.

76. (Previously presented) A cell line denoted as ATCC PTA-3305.

77. (Previously presented) A cell line denoted as ATCC PTA-3306.

78. (Previously presented) A cell line denoted as ATCC PTA-3307.

79. (Currently amended) A human monoclonal antibody or a CD40-binding fragment thereof, wherein the antibody is denoted number 72, which is produced by hybridoma ATCC PTA-2309.

80. (Currently amended) A human monoclonal antibody or a CD40-binding fragment thereof, wherein the antibody produced by a hybridoma denoted as F1-102 (ATCC PTA-3337).

81. (Currently amended) A human monoclonal antibody or a CD40-binding fragment thereof, wherein the antibody produced by a hybridoma denoted as F4-465 (ATCC PTA-3338).

82. (Currently amended) A human monoclonal antibody or a CD40-binding fragment thereof, wherein the antibody is denoted as F2-103, in which heavy chain of the antibody is produced by ATCC PTA-3302, and in which light chain of the antibody is produced by ATCC PTA-3303.

83. (Currently amended) A human monoclonal antibody or a CD40-binding fragment thereof, wherein the antibody is denoted as F5-77, in which the heavy chain of the antibody is produced by ATCC PTA-3304, and in which the light chain of the antibody is produced by ATCC PTA-3305.

84. (Currently amended) A human monoclonal antibody or a CD40-binding fragment thereof, wherein the antibody is denoted as F5-157, in which the heavy chain of the antibody is produced by ATCC PTA-3306, and, in which the light chain of the antibody is produced by ATCC PTA-3307.

85. (Currently amended) A detectably labeled human monoclonal antibody or a CD40 binding fragment thereof, wherein the antibody or fragment is the antibody or fragment of any of claims 82-84 ~~The human monoclonal antibody or fragment thereof of any of claims 82-84, wherein the antibody or fragment thereof is detectably labeled~~.

86. (Currently amended) A human monoclonal antibody, wherein the antibody comprises the heavy-chain variable sequence and the light-chain variable sequence of the antibody denoted as number 72, which is produced by hybridoma ATCC PTA-2309.

87. (Currently amended) A human monoclonal antibody, wherein the antibody comprises the heavy-chain variable sequence and the light-chain variable sequence of the antibody produced by a hybridoma denoted as F1-102 (ATCC PTA-3337).

88. (Currently amended) A human monoclonal antibody, wherein the antibody comprises the heavy-chain variable sequence and the light-chain variable sequence of the antibody produced by a hybridoma denoted as F4-465 (ATCC PTA-3338).